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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,797	01/30/2004	John T. Braun	4002-3068/PC798.00	7113

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KRIEG DEVAULT LLP  
ONE INDIANA SQUARE, SUITE 2800  
INDIANAPOLIS, IN 46204-2709

EXAMINER
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BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/768,797	Applicant(s) BRAUN ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06/27/2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-39,41-50 and 81-101 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,10-12,16,17,22-26,30,33,39,41-44,49 and 50 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81-101 is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9,13-15,18-20,27-29,31,32,34-38 and 45-48 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/17/2006; 8/21/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicants' amendment of claims 1, 2, 8, 18, 19, 22, 27, 37, 39, 45, and 46 in the reply filed on June 27, 2006 is acknowledged.
2. Applicants' cancellation of claims 40 and 51-80 in the reply filed on June 27, 2006 is acknowledged.
3. Applicants' addition of claims 81-101 in the reply filed on June 27, 2006 is acknowledged.

### ***Claim Objections***

4. Claim 90 is objected to because of the following informality:
  - a. Regarding claim 90, please substitute "being implantable in said second condition" (see line 4) with --being implantable between the first and second vertebrae in said second condition--.Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 91 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - a. Regarding claim 91, "said thickness" (see line 1) lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5, 8, 9, 13, 14, 18-20, 27-29, 32, 34-37, and 45-47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Elberg et al. (US 6,440,169 B1).

Referring to Figures 1-7, Elberg et al. disclose an implant comprising elastically deformable (see column 5, lines 28-35) body 6 made of a titanium alloy; a first anchor 2 comprising holes/apertures (U-shaped hole/aperture AND/OR holes 27) and teeth 25; a second anchor 2 comprising holes/apertures (U-shaped hole/aperture AND/OR holes 27) and teeth 25; a longitudinal axis (axis 5); a medial axis orthogonally oriented to said longitudinal axis (clearly shown in Figures 1-3) which medial axis includes an enlarged mid-portion; wherein said body includes a length extending between opposite first and second ends when said body is in a first condition, said body including a second condition wherein said body is longitudinally compressed between said opposite ends with said compressed length *sized for implanting* (emphasis will be added to functional language) said body, said body including means for reforming (e.g., elastically deformable material) from said second condition toward said length of said first condition when implanted and released from said compression. Once implanted, said body will either compress or extend/elongate, depending on the flexion and extension movements of the two opposite vertebrae, wherein the implant is configured and capable of reforming to an initial/original condition while exerting/maintaining distraction of said opposite

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vertebrae. As clearly shown in Figure 1, sides of the medial axis are triangular in shape. As disclosed in column 2, lines 25-33; column 4, lines 3-10; column 5, lines 2-10; the body includes a stiffness and thickness which varies along the length of the body, including a thickness that tapers from a medial portion of said body toward opposite ends of said body (see Figure 1).

9. Claims 1-5, 8, 9, 13-15, 18, 27-29, 31, 37, 38, and 45-48 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Perren et al. (US 6,019,793 A).

Referring to Figures 1-5, Perren et al. disclose an implant comprising a body made of a shape memory material; a first anchor (upper pyramidal teeth 8) capable of engaging to a first vertebra; a second anchor (lower pyramidal teeth 8) capable of engaging to a second vertebra; wherein the body has a length along a longitudinal axis (i.e., longitudinal axis of the spine column) extending between opposite first (upper plate 1) and second (second plate 1) ends; a medial axis orthogonally oriented to said longitudinal axis, which medial axis includes an enlarged mid-portion. As shown in Figures 4 and 5 (and disclosed at column 3, line 19 to column 4, line 2), the body is deformed/pressed/compressed from an initial state/condition (shown in Figures 1-3 and 5) to a second state/condition (shown in Figure 4) when implanted, and will reform/restore to said initial state/condition in order to exert/maintain distraction force between the first and second vertebrae. The body further includes holes in the first and second ends (see holes 5). The stiffness of the body varies along the length of the body, which is demonstrated by the thin portions and thicker portions, with an increased stiffness toward the median of the body.

10. Claims 1-5, 8, 9, 13, 14, 18-20, 27-29, 34-38, and 45-48 are rejected under 35

U.S.C. 102(b) as being clearly anticipated by Justis et al. (US 6,293,949 B1; cited in Applicants' IDS).

Referring to Figures 1, 3, 4a, 4b, 10, 11a, 11b, and 5-7, Justis et al. disclose an implant (system 20) comprising a body (member 22) made of a shape memory material; a first anchor 32 having bores 58, 66; a second anchor 32 having bores 58, 66; a longitudinal axis (axis L); a medial axis orthogonally oriented to said longitudinal axis, which medial axis includes an enlarged mid-portion; wherein said body includes a length extending between opposite first and second ends when said body is in a first condition, said body including a second condition wherein said body is longitudinally compressed (e.g., "prestressed"; see column 6, lines 65-67; column 11, lines 33-40) between said opposite ends with said compressed length *sized for implanting* (emphasis will be added to functional language) said body, said body including means for reforming (e.g., shape memory material) from said second condition toward said length of said first condition when implanted and released from said compression. Once implanted, said body will either compress or extend/elongate, depending on the flexion and extension movements of the two opposite vertebrae, wherein the implant is configured and capable of reforming to an initial/original condition while exerting/maintaining distraction of said opposite vertebrae (see column 12, lines 5-45 and lines 60-67). As clearly shown in Figures 3, 4a, and 4b, sides of the medial axis are triangular in shape (see column 7, lines 10-19). There are regions tapering in width from the medial axis toward each of the first and second ends of the body. The stiffness of the body varies along the length of the body, which is demonstrated by the presence of thin portions and thicker portions.

***Response to Arguments***

11. Applicant's arguments with respect to claims 1, 27, and 45 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

12. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 81-101 are allowed (note: dependent claim 91 has a 112 second paragraph rejection; see above).

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Holmes (US 5,415,661), Bertholet et al. (US 5,779,707), Castro (US 6,743,257), and Ritland (US 6,966,910).

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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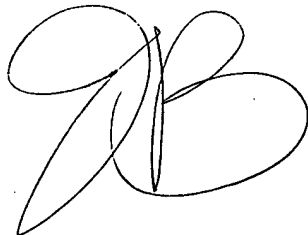
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

February 1<sup>st</sup>, 2007

  
David H. Willse  
Primary Examiner